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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/202,305 | 03/22/1999 | NICHOLAS MANOLIOS | 06025.0003 | 2721 |

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127 PEACHTREE STREET N E
ATLANTA, GA 30303-1811

EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,305

Applicant(s)

NICHOLAS MANOLIOS

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) 4, 9-11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) 5, 7-8, 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed, 11-29-02 is acknowledged. The amendment amended the specification. Claims 1, 3-14 are pending in this application.

Election/Restriction

2. Applicant's election with traverse of Group I and the species of SEQ ID. No. 7 in Paper No. 7 and 13 is acknowledged.

Thus, as indicated in the previous office action, allowability was established for the species corresponding to SEQ ID NO: 6-15 and 17-26. The search was extended in the Markush group and a peptide was found that read on generic claim 1. Although claims 4, 9-11 and 14 were examined with respect to SEQ ID. No 6-15 and 17-26, they were held as non elected since they did not read on the elected species found in the prior art. Note that under species examination a claim can be held, even though the elected species may have read on the said claim, as non-elected.

As stated in the previous office action, claims 1-3, 6, 13 have been examined to the extent they read on the prior art. Claims drawn to the nonelected species, claims 4, 9, 10-11, 14-15 are held withdrawn from further consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sitkovsky et al

The claims are drawn hydrophobic peptide and therapeutic composition thereof of which the below peptide are within the scope of the present claims for the reasons set forth in the previous office action and the reasons set forth below.

Applicants argue that the reference does not anticipate the claimed rejection. Applicants state that the peptide fragment PLR "contains the amino acid arginine (R), which is a charged amino acid. . .The specification requires a "hydrophobic peptide sequence. . .which does not include a charged amino acid."

Applicant's arguments filed 11-29-02 have been fully considered but they are not persuasive.

After reviewing Applicants arguments and upon further consideration, it is conceded that the peptide PLSRTLVSVS does not anticipate the claimed invention. However, the peptide PLRRTLSVAA still read on the claimed invention. The MPEP states clearly "[w]hile it is appropriate to use the specification to determine what the applicants intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not that limitation." *See MPEP 2106*. If applicants desire to have such a limitation, the limitation should be placed into the claims. Without the appropriate limitations, the MPEP routinely states that the broadest reasonable interpretation of the claims shall be made by office personal. *See MPEP 2106 and 2111*. It is not unreasonable to interpret the limitation of a claim reciting "hydrophobic peptide sequence" to mean a peptide sequence having a hydrophobic nature regardless of the fact that the peptide contain charged or uncharged amino acids. With this as a backdrop, the reference still anticipates the claimed invention since the peptide PLRRTLSVAA-NH₂ read on the claims. True that the PLR fragment contain a charged amino acid, but the peptide is still a hydrophobic peptide since it

contains two amino acids, out of three, that are hydrophobic. As stated in the previous office action, the R residue (the second R residue in the PLRRTL SVAA sequence) correspond the Z residue, TLSVAA read on the second X variable. The X variable comprise amino acids that are hydrophobic and are at least 50% of the amino acid making up the hydrophobic peptide (amino acids L, V, A constitute ~66% of the peptide).

Rejection is maintained.

4. Claims 5, 7-8, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

February 20, 2003

Brenda Brumback
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